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October 25, 2012

To: North Carolina Healthcare Providers and Healthcare Facilities
From: Megan Davies, MD, State Epidemiologist
Re: Guidance for Fungal Meningitis Outbreak and FDA Recommendations for Recalled Products – ***UPDATE #3***

This memo is intended to provide important information regarding the ongoing multistate outbreak of fungal meningitis and recent recommendations from the US Food and Drug Administration (FDA) regarding recalled products.

Updated Clinician Guidance for the Fungal Meningitis Outbreak

The North Carolina Division of Public Health (NCDPH) and other state and local health departments continue to gather detailed information about each case of fungal meningitis linked to contaminated lots of methylprednisolone. CDC is using this information to provide updated guidance to clinicians regarding risk, diagnosis, treatment, and follow-up of exposed patients.

These recommendations are evolving rapidly as we learn more about this rare disease. **Current information and clinical guidance are available at www.cdc.gov/hai/outbreaks/meningitis.html.** If you have additional questions, please do not hesitate to contact the North Carolina Division of Public Health at 919-733-3419.

FDA Recommendations for Recalled NECC Products

On September 26, 2012, the New England Compounding Center (NECC) issued a voluntary recall of the three lots of preservative-free methylprednisolone acetate implicated in this outbreak. On October 6, NECC expanded this voluntary recall to include all NECC products.

To date, there have been no confirmed cases of infection associated with NECC products other than the three lots of methylprednisolone acetate that were recalled on September 26, 2012. However, on October 15, 2012, FDA issued a statement advising healthcare providers to follow-up with patients who were administered any NECC injectable product on or after May 21, 2012**,** including any ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution purchased from or produced by NECC. On October 22, 2012, FDA updated its previous recommendation to state that providers should follow-up with patients when the following three conditions are met:

1. The medication was an injectable product purchased from or produced by NECC**,** including any ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution,
2. The medication was **shipped by NECC on or after May 21, 2012**, and
3. The medication was administered to patients on or after May 21, 2012.

Details about this FDA recommendation and lists of customers who received NECC products shipped on or after May 21, 2012 are available at www.fda.gov/Drugs/DrugSafety/FungalMeningitis/default.htm.

NCDPH does not anticipate providing any further communication about FDA recommendations directly to providers or facilities. As the FDA recommendations are subject to change, providers are encouraged to check the FDA website frequently for updates and to contact the FDA directly with questions or concerns. An FDA hotline is available at 855-543-DRUG(3784).